

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. Claim Status and Amendment

Claims 16, 18-23, 27, 38 and 40-42 were pending in this application when last examined and stand rejected. No claims have been allowed.

By way of the present amendment, claims 16, 19-20 and 38 have been amended to address the formal matters raised in the Office Action and to better conform to US claim form and practice. Claims 22-23, 27, 40-41 are as previously presented.

Claim 16 has been amended to incorporate the restrictor member and the lock member of claims 18 and 21 (now cancelled).

Claims 19 and 20 have been amended to depend on claim 16.

Claim 23 has been amended to better reflect that the rigid motion-restricting frame of the claimed cervical collar is adapted to fit any patient as supported by the general description throughout.

Claim 38 has been amended to incorporate the subject matter of claims 16, 18, and 21.

Claim 40 has been amended to better conform with US practice for antecedent basis.

Claims 18, 21, 28-37, and 42 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional on any cancelled subject matter.

No new matter has been added in the current amendment.

The present Amendment is being filed with a Request for Continued Examination (RCE) to thereby gain entry of the amendments herein.

Claims 16, 19-20, 22-23, 27, 38 and 40-41 are pending upon entry of this amendment.

The present Amendment is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

II. Claim Rejections under 35 U.S.C. §112, Second Paragraph

In item 1 on page 2 of the Office Action, claims 16 and 42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The claims have been amended to better define the claimed subject matter more clearly and distinctively in a non-narrowing manner to overcome this rejection for reasons which are self-evident. With respect to claim 16, the phrase "said jaw clasps" has been amended to the phrase "said jaw clasp". With respect to claim 42, said claim has been cancelled. The claims are thus clear, definite and have full antecedent basis.

Thus, this rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

III. Anticipation Rejection Under 35 U.S.C. § 102(b)

Claims 16, 18-23, 27, 38 and 40-42 remain rejected under 35 U.S.C. § 102(b), as being anticipated by Nagata et al. (US 5,575,763) for the reasons set forth in item 3 on pages 3-7 of the Action. This rejection is respectfully traversed.

The rejection should fall because Nagata fails to disclose each and every element of the claimed invention, as required to establish anticipation under 35 U.S.C. § 102. *See*, M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2131. Specifically, it is respectfully submitted that Nagata fails to disclose or suggest the "restrictor member" and "lock member" of amended claims 16 and 38.

Nagata discloses a cervical orthosis for supporting the cervical spine. According to Nagata, the primary object of the cervical orthosis disclosed therein is to provide extended long-term support for patients with spinal injury, so as to provide spinal support while at the same time allowing the patient to eat, talk, and perform other functions with ease and comfort.

At column 2 lines 35-38, Nagata clearly states: "[s]ince the cervical orthosis of the present invention does not restrain the mandible, the patient is able to comfortably open the mouth necessary in daily life, such as talking or eating a meal while wearing such a cervical orthosis" [emphasis added]. Hence, Nagata unmistakably states that the device disclosed therein is not intended to restrain the mandible (i.e., it is not intended to restrain the jaw).

Yet, on pages 6-7 of the Action, the examiner argues that the cheek brace pad 5 of Nagata corresponds to the claimed jaw clasp, which can be adjusted. Indeed, in the response to Applicants' arguments in the response filed August 3, 2009, the examiner contends that Applicants' arguments are unpersuasive because while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The examiner argues that there is no structural difference in the claimed device from that in Nagata. The examiner further argues if the prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then prior art meets the claims. In this regard, the examiner argues that the jaw clasp of Nagata is clearly capable of achieving the intended use as claimed, in light of the disclosure in Nagata at column 5, lines 10-13, of the VELCRO™ fastener affixed to the internal surface so that the cheek brace pads can be adjusted. In this regard, the examiner relies on the cheek brace pads of the cervical orthosis disclosed by Nagata as a means for maneuvering the jaw. Applicants respectfully disagree and submit that Nagata fails to disclose or suggest that for which it is being offered.

Nagata at column 4, line 65, to column 5, line 13, discloses

FIG. 3(c) illustrates the cheek brace pads 5, 5 when the cervical spine is not so injured. In such a case, the cheek brace pads each comprise a pad portion P, a resin-formed support plate for maintaining the lower end of the pad P in an L-shape so that the pad P can be along by the shape of the mandible, and VELCRO fastener affixed to the reverse surface of the support plate. The cheek brace pads are located to be in contact with the mandible. It should be noted that although the lower ends of the cheek brace pads are brought into contact with the mandible, such contact is not for restricting the movement of the mandible, but for urging it to separate from throat molds (throat pads), that is, for urging what is called, "the active correcting force". VELCRO fastener is preferably affixed to the internal surfaces of the front supporting portions 1b, 1b so

that the location of the cheek brace pads 5, 5 can be adjusted.
[Emphasis added.]

In other words, although Nagata discloses cheek brace pads 5, Nagata specifically states that "such contact is not for restricting the movement of the mandible".

Further, although Nagata also discloses a VELCRO™ fastener to be affixed to the internal surface of the front supporting portions, such that the location of the cheek brace pads could be adjusted; such VELCRO™ fastener does not allow easy and careful maneuvering of the jaw. Further, such VELCRO™ fastener does not enable a constant opened airway as does the jaw clasp with the restrictor member and the lock member of the claims of the present application.

It is respectfully submitted that from the above it can be concluded that Nagata does not intend to restrain the function of the jaw and maneuver the jaw, but only to adjust the location of the cheek brace pads. Thus, one of ordinary skill in the art would understand from this disclosure that Nagata does not even intend to restrain the function of the mandible, and any intention to maneuver the jaw clasp, which is attached to the mandible, would be contrary to the teachings of Nagata. As such, the examiner's reliance on the cheek brace pad 5 in Nagata as allegedly corresponding to the claimed jaw clasp as a means for maneuvering the jaw is incorrect, because this element in Nagata as it is not equivalent in structure and function to the claimed feature. Thus, Applicants respectfully submit that the VELCRO™ fastener and cheek brace pads in Nagata do not read on the jaw clasp, the restrictor member (for restricting the distance and the motion of said jaw clasp relative to said rigid motion-restricting frame), and the lock member (preventing backward motion of said jaw clasp relative to said rigid motion-restricting frame) of main claim 16.

Thus, contrary to the examiner's argument, the structural arrangement of the features of the device in Nagata is clearly different from that in the claimed device, and as a result, the prior art device in Nagata is not capable of performing the same function as the claimed device.

Again, the present application discloses and claims a cervical collar for maintaining the airway in the head and neck of an immobilized trauma patient and for simultaneously restricting the motion of the head and neck. In this regard, amended independent claim 16 reads as follows:

A cervical collar for restricting the motion of the head and neck of an immobilized trauma patient and for simultaneously opening and maintaining the airway of said patient by allowing motion of said jaw in a forward direction and restricting backward motion of said jaw relative to the neck of said patient, said cervical collar comprising:

- (a) a rigid motion-restricting frame attachable to the head for restricting the motion of the head in relation to the rest of the body of said patient,
- (b) a jaw clasp attachable to the jaw of said patient,
- (c) a restrictor member for restricting the distance and the motion of said jaw clasp relative to said rigid motion-restricting frame; and
- (d) a lock member preventing backward motion of said jaw clasp relative to said rigid motion-restricting frame,

wherein said cervical collar is adapted for restricting the motion of the head and neck, while simultaneously maneuvering said jaw by way of said jaw clasp, said restrictor member and said lock member, in a forward and slightly downward direction such that airway maintenance with cervical spin control is provided.

As can be seen, the claims of the instant application clearly require that the various structural elements be arranged so that the cervical collar is adapted for restricting the motion of the head and neck, while simultaneously maneuvering said jaw via said jaw clasp, said restrictor

member and said lock member, in a forward and slightly downward direction such that airway maintenance with cervical spin control is provided. Nagata fails to disclose or suggest such features.

Further, it should be noted that easy and careful maneuvering of the jaw via a jaw clasp, a restrictor member and a lock member in a forward and slightly downward direction is critical to maintain the airway of the patient open in an emergency situation.

Providing such jaw maneuvering by restricting the distance and the direction of motion of said jaw clasp relative to said rigid motion-restricting frame and by preventing backward motion of said jaw clasp relative to said rigid motion-restricting frame is the core concept of the claimed invention.

Since the cervical orthosis of Nagata is not structurally arranged to restrain the jaw and it cannot enable open airways, it is not suitable for emergency trauma settings, as is the device of the claimed invention. This is important because in emergency trauma situations, it is not enough to simply restrain the neck without restraining the mandible. If this cannot be done, added measures must be taken in order to assure that the airway remains open since there exists a danger of loosing consciousness and an automatic closure of the airways. For example, supraglottic airway obstruction is very common due to either unconsciousness or, less frequently, to direct trauma. Endotracheal intubation is considered the gold standard for securing the airway. Other less invasive methods, such as laryngeal mask, oral or nasal airway, or other more invasive procedures, such as, cricothyroidectomy are also used in order to assure that airway remains open.

It is also not enough to simply leave the mandible unrestrained, as in the case of Nagata. Nagata provides a solution for every-day life situations where the patient is fully conscious, in order to allow for easier eating and speaking. However, the device in Nagata is

not satisfactory in trauma situations where, even if the mandible is unrestrained, the airway could close due to loss of consciousness. The unrestrained mandible is likely to fall backward in the direction of the airway (the oro-pharings) and thus blocking and closing the airway.

Using the cervical collar of claim 16, however, the mandible is actively pushed forward in the opposite direction, thus opening the airway. This novel effect is provided by the unique and novel structural arrangement of the various elements in the device of the present claims, which is neither provided nor taught in Nagata.

Also, the airway-protecting cervical collar of the claims is designed for both supporting the cervical spine and for actively keeping the airway open. The jaw clasp of the device both allows and promotes forward movement of the jaw so as to maintain open airways, and, where needed, allows for an easy performance of jaw thrust maneuvers.

Based on the above, Applicants again respectfully submit that contrary to the examiner's argument, the structural arrangement of the features of the device in Nagata is clearly different from that in the claimed device, and as a result, the prior art device in Nagata is not capable of performing the same function as the claimed device. Further, it should be noted that the examiner's arguments relate solely to the apparatus claims. They do not address the methods of claims 38, 40, and 41.

For these reasons, Applicants respectfully submits that Nagata fails to disclose each and every feature of amended independent claims 16 and 38; and Nagata does not even intend to maneuver the jaw clasps in a forward and slightly downward direction, as recited in claims 16 and 38. Therefore, claims 16 and 38 are novel and patentable over Nagata, and dependent claims 18-23, 27, and 38-42 are also patentable by virtue of their dependency from claim 16, and the features recited therein.

For these reasons, the anticipation rejection over Nagata is untenable and should be withdrawn. Withdrawal of the rejection is respectfully requested.


IV. Conclusion

In view of the above amendment and remarks, Applicants respectfully request withdrawal of the outstanding rejections of record. Applicants submit that the application is in condition for allowance and early notice to this effect is most earnestly solicited.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By 
Jay F. Williams
Registration No. 48,036

JFW:pp
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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